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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,451	08/24/2006	Mika Jokinen	TUR-186	8475
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JAMES C. LYDON				
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ALEXANDRIA, VA 22314				
EXAMINER				
WHEELER, THURMAN MICHAEL				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/590,451

Applicant(s)

JOKINEN ET AL.

Examiner

THURMAN WHEELER

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 51-58 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 51-58 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-133)
Paper No(s)/Mail Date 06/08/2011
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/24/2010 and 12/31/2010 have been entered.

This application has been assigned to a different examiner.

1. Claims 51-58 are pending.
2. Claims 1-50 have been cancelled.
3. Claims 51-58 are newly added.
4. Herein, claims 51-58 are for further prosecution.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 06/08/2011 has been considered by the examiner and an initialed

copy of the IDS is included with the mailing of this office action.

Claim Objections

6. Claim 51 is objected to because of the following informalities: claim 51: 3) a) (page 5) the word 'thein' is inappropriate. It appears that this sentence should read as follows: . . . rate in a TRIS buffer . . . Appropriate correction is required.

Rejections Maintained

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining differences between the prior art and claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. The rejection of newly added claims 51-58 under 35 U.S.C. 103(a) as being unpatentable over Kortesuso (Dissertation, University of Helsinki, 2001, of record) as evidenced by Kortesuso (a) et al, 2001 (Journal of Controlled Release, vol. 76:227-238, of record) is maintained.

9. Applicant's claimed invention is directed to a bioresorbable sol-gel derived SiO₂, wherein said SiO₂ is prepared by correlating a desired biodegradability of SiO₂ with changes 1), 2) and/or 3) to a method of preparing a SiO₂ from a sol comprising water, an alkoxide or inorganic silicate and a lower alcohol with <4 carbons, using a mineral acid or a base as a catalyst, aging said sol and drying said sol, and further, in accordance with claim 51.

10. Claims 51-58 are product-by-process claims. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. "In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Furthermore, patentability

determination of a product-by-process claim is based on the structure imparted to the product by the process steps. When there is no physical evidence to support or a reason to believe that a patentably distinct structure is imparted by the process steps, the burden of proving otherwise falls to the Applicants'. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. See MPEP § 2113.

Kortesuo teaches sol-gel derived silica gel monoliths were prepared by casting while microparticles were prepared by spray drying. Kortesuo teaches that the silica xerogel materials used were biodegradable and did not cause any adverse effects in the surrounding tissue or various organs in the preliminary study with mice. Kortesuo teaches silica xerogel was shown to be suitable for controlled delivery of drug substances both as an implantable and an injectable drug delivery system. (Abstract).

Further, Kortesuo teaches the effects of sol-gel synthesis parameters (pH of the sol, water/TEOS ratio and partial substitution of silica precursor with alkyl-substituted alkoxide) on the release behaviour of biologically active agents (p.19, parts 1 and 2).

Particularly, Kortesus teaches a biodegradable (p.25, section 5.1.2) sol-gel derived SiO_2 monolith (p.10, section 2.3, paragraph 1 and p.25, section 5.1.2) which can incorporate cells (p.11, paragraph 1). Kortesus teaches degradation studies were performed at pH 7.4 and at 37° C in simulated body fluid (SBF) (p.22, section 4.4, paragraph 1) and as evidenced by Kortesus (a), SBF contains TRIS buffer (p.228, column 2, section 2.3, paragraph 1).

Kortesus teaches the amount of silica xerogel degraded after 30-hours of dissolution was at least 15% for a disc-shaped monolith (diameter 4.6 mm) and at most 28% for a rod-shaped monolith with a 0.95 mm diameter (III, fig 4 b) (see p.25, 5.1.1, paragraph 2), which provides a dissolution rate of about 0.5 to 0.9 weight percent per hour. Further, Kortesus teaches degradation time of a monolith as low as 4 days (i.e. 100 percent dissolution in 96 hours at pH 2.3, or greater than 1 percent per hour) or as high as 4 months (i.e. about 0.037 weight percent per hour) (p.35, section 6.1.3).

Kortesus teaches that the optimum release profile for a biologically active agent was obtained from silica gels (monoliths and microparticles) prepared at pH = 2.3 where the structure of silica gel is most condensed). Kortesus teaches that the water/TEOS ratio affects the structure of silica gel

monoliths and a more condensed matrix is formed at low water/TEOS ratios (See p.32, 6.1.1). Furthermore, Kortesus teaches the pH and the water to alkoxide (or inorganic silicate) ratio affects the degradation rate (p.28, table 2) as does the surface area and geometry of the sol-gel derived SiO_2 (p.7, paragraph 3). Kortesus also teaches the porous structure alters the degradation rate of the sol-gel derived SiO_2 monolith (p.31, section 6.1) and larger gel monoliths degrade faster than smaller ones (p.35, section 6.1.3, paragraph 2). Kortesus teaches the water/alkoxide to alcohol ratio also affects the silica xerogel microstructure (p.12, section 2.3.1). Kortesus also teaches the degradation rate of the silica xerogel can be modified by varying the composition of starting materials and subsequently the structure of the silica gel matrix by varying the manufacturing method from casting to spray drying (p.35, section 6.1.3, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time to provide a sol-gel derived SiO_2 monolith having desired biodegradability by optimizing the surface area (particle diameter), porosity, pH and the water/alkoxide ratio by following the guidance provided from the teachings of Kortesus.

As MPEP 2144.05 recites 'where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization'.

Further, it would have been obvious to one skilled in the art at the time of the invention to use the sol-gel derived monoliths to deliver any biological agent of interest especially heat sensitive agents as taught by Kortesuso (Abstract, page iii) including cells, peptides and proteins (p.13, 2.3.2). Moreover, one skilled in the art at the time of the invention would have been motivated to do this because Kortesuso teaches the sol-gel derived SiO₂ monoliths are a means to control the release rate of therapeutic substances (p.31, section 6.1, paragraph 1).

Thus, one skilled in the art at the time of invention would have had a reasonable expectation of providing a sol-gel derived SiO₂ monolith having desired biodegradability by following the teachings of Kortesuso.

Accordingly, the claimed invention was prima facie obvious to one skilled in the art at the time of the invention was made especially in the absence of evidence to the contrary.

Response to Arguments

11. Applicants argue that the claim changes made by this preliminary amendment serve to put the application in better form for examination by (i) correcting dissolution ranges, (2)

adding structural features to the SiO₂ monolith, coating and particle, and (3) presenting generic claims so that examination of the non-elected species claims will be in order when the monolith species is found patentable

Applicant's arguments filed 31 December 2010 have been fully considered but they are not persuasive, because applicant's claimed invention is still deemed obvious in view of the teachings of Kortessuo as set forth above.

Conclusions

12. No claims are allowed.

13. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on 9:00 a.m.-5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached (571)272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T.W.

/Anne M. Gussow/

Primary Examiner, Art Unit 1643